

NIHON KOHDEN AMERICA, INC.
April 1, 1996

510(k) NOTIFICATION
ECG-9320A CARDIOFAX

NOV - 1 1996

K961272

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant

Nihon Kohden America, Inc.
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Contact Person and Telephone

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Director of Technical Operations
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The device has been classified as Class II by the Division of Cardiovascular, Respiratory, and Neurological Devices and the Cardiovascular Device Classification Panel under 21 CFR Part 870.2340 "Electrocardiograph" as per part 74 DPS, 21 CFR.

Common names for the ECG-9320A Cardiofax device include electrocardiograph and Cardiograph.

The predicate devices are the Nihon Kohden Cardiofax, ECG-8340A Electrocardiograph per 510(k) #K865032, commercial distribution certification dated March 10, 1987 and the Hewlett-Packard M1700A PageWriter XLi Cardiograph per 510(k) #K895520, commercial distribution certification dated July 17, 1990

Nihon Kohden's Cardiofax, model number ECG-9320A, is intended for medical purposes used to process the electrical signals transmitted through two or more electrocardiograph electrodes and to produce a visual display and prepare a record of the electrical signals produced by the heart. This product will be available for use by a physician within the hospital, laboratory, clinic or in a remote environment under the direct supervision of a physician.

To date, no performance standards or special controls are known or established for this device as required by Section 514 of the Food, Drug and Cosmetic Act and implemented by 21 CFR Part 861.

The ECG-9320A Cardiofax device was subject to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Software validation tested the operation of the software functions of acquiring, processing, displaying and recording of all functions of the device. The results confirmed that the device performed within specifications.

Therefore based on the above, Nihon Kohden believes that the ECG-9320A Cardiofax is substantially equivalent to the Nihon Kohden ECG-8340A Cardiofax and the Hewlett-Packard M1700A PageWriter XLi cardiograph.